CERTIFICATE OF ELECTRONIC TRANSMISSION
37 C.F.R. § 1.8

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November 17, 2009
Date

Steven L. Highlander

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Malte PETERS *et al.*	Group Art Unit: 1641
Serial No.: 10/589,450	Examiner: Bradley Duffy
Filed: August 11, 2006	Atty. Dkt. No.: DEBE:069US
For: ANTI-EPCAMIMMUNOGLOBULINS	Confirmation No.: 5684

DECLARATION OF NADJA PRANG UNDER 37 C.F.R. §1.132

I, the undersigned, do declare that:

1. I am a German citizen residing in Montfort L'Amaury, France. I am a named inventor on the above-captioned application.

2. I currently hold the position of Program Director Monoclonal Antibodies at LFB in France. From June 1st 2002 to December 31st 2004, I hold the position of Director Bioanalytics at Micromet, the assignee of the above-captioned application. My research experience includes over 1o years of biotech product development in various International Companies. A copy of my *curriculum vitae* is attached.

3. I have reviewed the Office Action of July 17, 2009 regarding the above-captioned application, as well as the Kufer, Raum, Naundorf, Oberneder, Loh, Leyland-Jones and Riethmüller references cited therein. It is my understanding that the examiner believes that an administration protocol of no more frequent than every two weeks is obvious over the combined teachings of the aforementioned references.

4. I understand the version of claim 1 that is to be submitted in response to the August 17, 2009 office action will recite the following:

> A method of treating, in a human patient, a malignant tumorous disease characterized by EpCAM expression elevated relative to healthy state of a given tissue comprising administering to said patient a human antibody comprising a heavy chain with the amino acid sequence of SEQ ID NO: 1 and a light chain with the amino acid sequence of SEQ ID NO: 2, wherein said human antibody specifically binds to the human EpCAM antigen, said method comprising the step of administering said human antibody once every one to two weeks in order to treat said malignant tumorous disease.

I can confirm SEQ ID NO:1 and SEQ ID NO:2 are sequences of a particular human antibody, MT201. Moreover, the claim recites administration at intervals of 1-2 weeks.

5. It is my understanding that the examiner argues that Kufer discloses the same the MT201 antibody as claimed here, and in light of teachings cited therein (Riethmüller) relating to monthly administration of a murine antibody to EpCAM, it would be obvious to administer MT201 no more frequently than every two weeks. I do not agree.

6. First, the properties of a mouse antibody to EpCAM (17-1A or Panorex®) are not directly applicable to a human antibody against the same target (MT201).

7. Second, the murine antibody Panorex® of Riethmüller was provided to subjects using once a month administration regimen. Yet as is evident from FIG. 18, Example IV.4. of Kufer, MT201 (a.k.a. H79) shows much higher cytotoxic activity than Panorex®. Further, Raum discloses the beneficial properties of MT201, namely, a long *in vivo* half-life and minimal immunogenicity, and confirms the differences between MT201 and the 17-1A antibody of Riethmüller in cytotoxic activity (see page 146, right column second paragraph and Figure 5). One of skill in the art would not seek to ***increase*** the frequency of administration of MT201 over that of Panorex® when the former had a higher cytotoxic activity as compared to the latter. Rather, one of skill in the art would choose a ***less frequent*** administration schedule for MT201, quite the opposite of what is now claimed.

8. Finally, I also generally disagree with the examiner's statement that establishing a particular dosing regimen for an antibody therapy is a matter of mere optimization.

9. In sum, when viewing the cited art discussed above, I do not believe that the treatment regimen of claim 1 above would have been readily suggested to those of ordinary skill in the art. While optimizing treatment regimens is always a desirable goal, it is quite unpredictable what regimens will provide improved results, if any.

10. I hereby declare that all statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

4th November 2009
Date

N. Prang-Richard
Nadja Prang-Richard, Ph.D.